Collaborator Press Release: Long-Term Survival After Breast Cancer Diagnosis May Depend on Gene Expression

CHICAGO May 31, 2003 — Most breast cancer patients with more than 10 nodes that are affected by the cancer have a poor prognosis, yet some survive long-term. Physicians now believe that certain genes in the breast cancer tissue, removed at diagnosis, can help them predict which patients will survive.

With this information, doctors can recommend the most appropriate therapy for an individual patient, for example sparing a woman with a poor prognosis the rigors that accompany aggressive chemotherapy, and enabling her to receive novel treatments that might work, according to Dr. Melody Cobleigh, oncologist, professor of medicine and director of the Comprehensive Breast Center at Rush-Presbyterian-St. Luke's Medical Center in Chicago.

Cobleigh presented her research results on May 31 at the American Society of Clinical Oncology Annual Meeting in Chicago.

Until now, such studies could only be performed on recently biopsied tissue that would then be frozen for preservation. Routine handling of cancer specimens does not involve freezing. Cobleigh and colleagues at Genomic Health examined the breast cancer tissue of 79 patients who had been treated at Rush between 1979 and 1999 and whose tissues had been processed in the usual manner (formalin-fixed and paraffin-embedded). The patients had been followed for a median of 15 years.

Expression of 185 cancer-related genes was assessed. The genes chosen were based on previous reports on frozen tissues. Cobleigh determined that those women whose tumors expressed excess amounts of some genes, e.g. TP53BP2, PR and Bcl2, were more likely to be free of cancer in their vital organs. She also found that women whose tumors expressed too much of other genes, e.g. GRB7, CTSL and DIABLO experienced a worse outcome. Cobleigh reported that even among women with 10 or more positive nodes, the gene expression profile could predict long-term survival.

"Until now, the only indications we have had of long-term prognosis were tumor size and the number of involved nodes," Cobleigh said. "This technology will allow us to tailor a prognosis to the individual patient, using information from thousands of genes."

She cautioned, however, that her research is a first step. "These findings must be confirmed in independent data sets," she said. She pointed out, however, that this is already underway, using material from tumor banks owned and managed by international cooperative groups, such as the National Surgical Adjuvant Breast and Bowel Project (NSABP), which is a clinical trials cooperative group supported by the National Cancer Institute (NCI). If results are validated, the test could become commercially available within a year.

Cobleigh, who was an investigator in the 1990s on the clinical trials to test the monoclonal antibody Herceptin, suggested that another offshoot of this work is to examine the tumor for expression of genes that will predict responsiveness to specific therapies, such as Herceptin.

Tumor tissue for this research was generated from the Bill Shorey Database of Breast Tumors, named after Dr. Bill Shorey, a breast surgeon who worked at Rush for more than 30 years. The Shorey Database was computerized by Dr. David Roseman, another surgeon who worked at Rush for over 30 years, and Michigan physician Dr. Craig Silverton.

Rush-Presbyterian-St. Lukes Medical Center includes the 824-bed Presbyterian-St. Lukes Hospital; 110-bed Johnston R. Bowman Health Center; Rush University (Rush Medical College, College of Nursing, College of Health Sciences and the Graduate College).

Founded in August of 2000 and located in Redwood City, California, Genomic Health, Inc. is building an oncology-based health care services company for physicians and patients to provide individualized genomic analysis of tumor biopsies. Genomic Health has pioneered the use of high-throughput analysis of fixed paraffin-embedded tissues to obtain and clinically validate genomic information in large-scale clinical trials. Genomic Health is using this extensive clinical experience to develop validated genomic services to provide individualized information on the likelihood of disease recurrence and response to therapy. Genomic Health's goal is to improve the quality of treatment decisions for patients with cancer. Genomic Health has the financial backing of some of the world's leading capital and financial institutions, including Kleiner Perkins, JP Morgan, Versant Ventures, Texas Pacific Group and Baker Tisch.